NOV 1 5 2013

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: July 26, 2013

Submitter: GE Healthcare, (GE Medical Systems, LLC)
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Waukesha, WI 53188

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Device: Trade Name: Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, and Optima MR450w 1.5T

Common/Usual Name: Magnetic Resonance Diagnostic Device

Classification Names: 892.1000

Product Code: LNH

Predicate Device(s): Discovery MR750w 3.0T [K130115]

Optima MR450w 1.5T [K123522]

Device Description: The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T Systems are whole body magnetic resonance scanners designed to support high resolution, high signal-to-noise ratio, and short scan times. The Systems each feature a superconducting magnet. The data acquisition system accommodates up to 32 independent receive channels in various increments and multiple independent coil elements per channel during a single acquisition series. Each system uses a combination of time-varying magnetic

fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. Each system can image in the sagittal, coronal, axial, oblique, and double oblique planes, using various pulse sequences and reconstruction algorithms.

The DV24 release is introducing new software features onto these existing MR Systems. There are also hardware modifications to the GEM configurations for Silenz compatibility. The Silenz feature used to reduce the acoustic noise generated during an MR examination is only available on the Optima MR450w GEM and Discovery MR750w GEM configurations.

The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T Systems are designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Intended Use: The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems are whole body magnetic resonance scanners designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Technology: The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T Systems with the addition of the new features employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems with the addition of the new software features complies with the following voluntary standards:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-1-6
- IEC 60601-2-33
- IEC 62304
- IEC 62366
- ISO 14971

In addition, these MR scanners are in compliance with the applicable NEMA standards, including NEMA PS3.1-3.20 for DICOM conformance.

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Verification testing for the new software features has been completed with passing results.

Summary of Clinical Tests:

The subject of this premarket submission, Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T, did not

require external clinical studies to support substantial equivalence. Internal scans were conducted as part of validation for workflow and image quality for the addition of the new features. The clinical results demonstrated that the Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T maintain the same imaging performance results as its predicate devices (K123522 and K130115). Sample clinical images are included in this submission.

Conclusion: GE Healthcare considers the Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T with the addition of the new features introduced in the DV24 software release to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 15, 2013

GE HEALTHCARE (GE MEDICAL SYSTEMS, LLC)
% MICHELLE HUETTNER
REGULATORY AFFAIRS LEADER, MAGNETIC RESONANCE
3200 N. GRANDVIEW BLVD
WAUKESHA WI 53188

Re: K132376
Trade/Device Name: Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, Optima MR450w 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 20, 2013
Received: August 26, 2013

Dear Ms. Huettner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

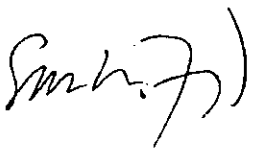
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132376

Device Name
Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and Optima MR450w 1.5T

Indications for Use *(Describe)*
The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems are whole body magnetic resonance scanners designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*